

REMARKS

Applicant respectfully requests reconsideration. Claims 46-71 were previously pending in this application with claims 46, 53, 59, and 65 being independent claims. The specification and claims 46, 53, 59, and 65 have been amended. No new matter has been added.

Applicant again acknowledges the courtesies extended by Examiner Pellegrino during a telephone discussion with the undersigned attorney on March 30, 2007. The substance of the discussion is summarized in the remarks set forth below.

Applicant respectfully traverses each of the rejections presented in the Office Action of December 19, 2006 for reasons similar to those set forth in their prior responses of April 11, 2007, September 19, 2006, May 21, 2004 and December 23, 2003 and the declaration of Stephan N. Eldridge (hereafter the "Eldridge Declaration") submitted therewith, which are incorporated herein by reference.

Rejections Under 35 U.S.C. § 102

Rejections in View of Mulhauser

Claims 46, 47, 50, 54-56, 59-62, 65-68 and 71 stand rejected under 35 U.S.C. §102(b) as purportedly being anticipated by Mulhauser (U.S. patent No. 5,695,525). The Examiner contends that Mulhauser discloses (Figs. 4a, 4b) a surgical repair material comprising a fabric 34, a barrier layer 36 and an edge barrier 32. The Examiner further contends that Mulhauser illustrates (Figs. 2a, 2b, 3h) a frame structure located at the edge to form an edge barrier. Applicant respectfully traverses these rejections.

As previously pointed out, Mulhauser '525 is a family member of Mulhauser '246 (US 5,766,246) which was previously applied during prosecution of the claims and over which the claims were found to be patentable. Applicant respectfully asserts that the claims patentably distinguish over Mulhauser '525 for at least the same reasons set forth in the prior responses.

Independent claims 46, 59 and 65 recite, *inter alia*, a prosthesis or repair fabric with an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier isolates or covers at least a portion of the edge of the fabric.

Mulhauser is directed to an implantable prosthesis 10, 30 having a mesh layer 12, 34 and a semi-rigid frame or ring 14, 32 supporting the mesh layer. (Mulhauser '525, Col. 3, lines 42-

53; col. 5, lines 24-29). In the embodiment shown in Figs. 4a-4b, the fabric extends outwardly beyond the frame or ring 32 such that the frame 32 does not cover or isolate a portion of the fabric edge. Consequently, the frame 32 is not an edge barrier as recited in the claims for at least this reason.

In the Office Action, the Examiner contends that:

the support frame 32 clearly isolates a portion of the edge or covers a portion of the edge since the claims do not set forth what an edge is defined as. (Office Action, page 4).

The Examiner further contends that:

Since the claims do not set forth any special definition of "edge" it can be construed that since Mulhauser's frame is at the outer periphery of the fabric it is covering or isolating the edge. (Office Action, page 4.).

Applicant respectfully asserts that one of ordinary skill in the art would readily understand the term "edge" to be a narrow surface extending between the major surfaces of the fabric based on the plain meaning of "edge" and further in view of the specification which is consistent with the plain meaning of the term. Additionally, the claims recite that the fabric includes opposing first and second sides and an edge extending between the first and second sides. Therefore, one of ordinary skill in the art would understand the meaning of "edge" as set forth in the claims and further recognize that the frame 32 shown in Figs. 4a-4b of Mulhauser does not cover or isolate a portion of the fabric edge.

Nevertheless, as indicated in the Office Action, Mulhauser does disclose a prosthesis (Figs. 2) which includes a frame that covers the edge of the mesh fabric. As shown in Figs. 2 and 3(h), the frame 14 may be configured to extend over the mesh layer at both the peripheral edge of the mesh layer and the surface margin of the mesh layer adjacent the peripheral edge. However, as explained previously, Mulhauser does not teach or suggest that the frame 14, 32 has any type of adhesion inhibiting properties.

In the Advisory Action, the Examiner asserts that Applicant's above arguments concerning whether or not the Mulhauser frame covers a portion of the fabric edge are contradictory. Applicant respectfully disagrees.

As discussed above, the Examiner indicated in the Office Action that Mulhauser discloses, as shown in Figs. 4a, 4b, a surgical repair material comprising a fabric 34, a barrier layer 36 and an edge barrier 32. Applicant respectfully asserts that this particular embodiment of

Mulhauser does not disclose a frame or other structure that isolates or covers at least a portion of the edge of the fabric as set forth in the claims.

In the Office Action, the Examiner contends that the claimed physical properties are purportedly present in the prior art material (edge barrier) to some extent even though they are not explicitly recited. (Office Action, page 2). Based on this contention, the Examiner attempts to shift the burden to Applicant to show that the frame does not have adhesion resistant properties. (Office Action, pages 2-3). However, as indicated previously, this is not the proper test for establishing a rejection based on inherency. Rather, the burden lies with the Patent Office to provide rationale or evidence that the Mulhauser frame inherently possesses the claimed adhesion resistant properties.

As explained in MPEP §2112(IV):

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. Citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original).

To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' Citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

In an apparent attempt to provide a rationale or evidence to establish that the Mulhauser frame is inherently adhesion resistant, the Examiner contends that the frame is solid or rigid to provide support to the fabric and thus would inhibit adhesions from forming. (Office Action, page 3). Thus, it appears that the Examiner contends that a solid or rigid frame is inherently adhesion resistant. Applicant respectfully disagrees.

As discussed previously and again indicated during the telephonic discussion, Applicant previously submitted a declaration to show that the Mulhauser frame does not inherently possess adhesion resistant properties. (See Eldridge Declaration). Silicone or polypropylene materials, which Mulhauser discloses may be employed for the ring or frame, do not inherently or necessarily inhibit adhesions. The adhesion resistant properties of a soft tissue repair prosthesis

are affected by various factors such as the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. (See Eldridge Declaration, paragraph 9). Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. (See Eldridge Declaration, paragraph 9). For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately $10\mu\text{m}$ or more is susceptible to adhesions with tissue or muscle. (See Eldridge Declaration, paragraph 9).

Applicant previously provided several references (Woodward, "The Tissue Response to Implants and Its Evaluation by Light Microscopy" and Boyers, "Reduction of postoperative pelvic adhesions in the rabbit with Gore-Tex surgical membrane") describing the surface texture and porosity characteristics of an implantable material as these characteristics relate to the adhesion resistance of the material. The Woodward reference (page 370, right column) discloses that surface irregularities as small as $10\text{-}15\mu\text{m}$ result in the development of giant cells as the principal cellular interface between the host and non-reactive implant. Thus, Woodward indicates that a material with surface irregularities of approximately $10\mu\text{m}$ or more is susceptible to adhesions with tissue or muscle. The Boyers reference discloses that an implant manufactured with a relatively large pore size encourages tissue attachment and the infiltration of fibers into its microstructure, while an implant having an average pore size less than or equal to $1\mu\text{m}$ minimizes cellular penetration and tissue attachment. (Boyers, page 1069, left column).

Mulhauser provides no teaching or suggestion as to any structural characteristics of the frame that would determine its adhesion resistant properties. The surface texture and porosity of a silicone frame (as well as a molded polypropylene frame) can vary depending on the specific design parameters of the mold used to form the frame. (See Eldridge Declaration, paragraph 10). Therefore, a molded silicone frame can promote tissue ingrowth and adhesions with tissue and muscle. (See Eldridge Declaration, paragraph 10). Thus, although the Mulhauser frame may be molded from a silicone material, this does not necessarily provide a frame that inhibits adhesions to tissue and muscle, such that one of ordinary skill in the art would not consider the Mulhauser frame, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. (See Eldridge Declaration, paragraph 10).

In the Office Action, the Examiner stated that:

In response to applicant's argument that both Meier and Mulhauser fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., porosity less than 10µm) are not recited in the rejected claim(s). However, it should be noted that this limitation is not supported by the disclosure and thus the Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. . . Since the disclosure fails to define any special porosity for the edge barrier, it can be said that since both Meier's and Mulhauser's edge barriers are solid materials and not an open structure they clearly can prevent adhesions. (Office Action, pages 4-5).

As explained during the telephonic discussion, Applicant is relying upon the limitation that the edge barrier "inhibits the formation of adhesions with sensitive tissue and organs thereto." As discussed above and set forth in the Eldridge Declaration, one of ordinary skill in the art understands and would interpret this limitation as requiring the edge barrier to have particular characteristics, including porosity and surface texture characteristics, which render the barrier adhesion resistant. As discussed with the Examiner, Mulhauser fails to disclose any particular structural characteristics for the frame, such as surface texture or porosity, that would enable one of ordinary skill in the art to conclude that the Mulhauser frame inherently inhibits the formation of adhesions thereto.

As also explained during the telephonic discussion, the specification clearly supports the claim limitation that the peripheral barrier inhibits the formation of adhesions thereto. Further, this feature is enabled by the specification which discloses several examples of materials that are adhesion resistant.

In response to Applicant's arguments concerning the characteristics of an adhesion resistant material or structure, the Examiner further stated the in Advisory Action that:

Applicant's disclosure provides no description of structural characteristics of a material that would inhibit adhesions. . . The Examiner does acknowledge the arguments or points referred to by the declaration discussing adhesion resistant materials and also the new documents cited in the response submitted herein. However, these are all irrelevant since none [of] the subject matter presented in the declaration or in the NPL documents to describe a material

that would promote adhesions was originally present in Applicant's disclosure.

Applicant respectfully disagrees with the Examiner's assertion that the Eldridge Declaration and the Woodward and Boyers references are irrelevant. Although the specification did not expressly disclose that an adhesion resistant barrier has a surface texture and a porosity that are less than 10 μ m, these documents clearly establish that one of ordinary skill in the art would understand that an implantable structure or material that inhibits the formation of adhesions thereto inherently possesses these characteristics. Applicant has amended the specification to expressly provide this description and has also amended claims 46, 59, and 65 to further recite that both the barrier layer and the edge barrier have a surface texture and a porosity that are less than 10 μ m. Applicant respectfully submits that this description and these limitations are not new matter as the originally filed application inherently included this disclosure.

In view of the foregoing, claims 46, 59 and 65 patentably distinguish over Mulhauser, such that the rejections under §102 should be withdrawn. Mulhauser does not disclose an adhesion resistant edge barrier having a surface texture and a porosity that are less than 10 μ m as recited in each of the claims.

Claims 47 and 50, claims 60-62, and claims 66-68 and 71 respectively depend from claims 46, 59 and 65 and are patentable for at least the same reasons. It is unclear as to the basis for the rejection of claims 54-56 as they depend from claim 53 which has not been rejected in view of Mulhauser. Nevertheless, claim 53, which also recites an edge barrier as discussed further below, patentably distinguishes over Mulhauser for at least the same reasons as independent claims 46, 59 and 65, and claims 54-56 are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

Rejections in View of Meier

Claims 53, 56, 65, 68 and 71 stand rejected under 35 U.S.C. §102(b) as purportedly being anticipated by Meier (U.S. patent No. 3,416,524). The Examiner contends that Meier shows (Fig. 2) a surgical repair material comprising a fabric 15, a barrier layer 14 and an edge barrier 12. Applicant respectfully traverses these rejections.

Independent claim 65 is discussed above.

Independent claim 53 recites, *inter alia*, an implantable prosthesis comprising a repair fabric and an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier covers at least a portion of the edge of the fabric.

Meier is directed to a non-adherent surgical dressing including a laminated pad 13 with a cellulosic layer 14 and a resin fiber layer 15 which are joined by needled resin fibers 16 using a needling and heat fusion process. The cellulosic layer has moisture absorption properties while the resin fiber layer has a porous surface which serves as the non-adherent contact surface for the wound and which permits free flow to moisture. The pad is surrounded by an edge frame or crown 12 which stabilizes the edges of the cellulosic layer and the resin fiber layer.

As explained previously, Meier does not teach or suggest that the frame has any type of adhesion inhibiting properties. Rather, Meier discloses that frame provides freedom from fraying, loose fibers, delamination and the like by surrounding and stabilizing the edges of the cellulosic layer and the resin fiber layer. (Col. 2, lines 51-56). Meier indicates that the frame may be fabricated from any of a variety of materials, such as an inert thermoplastic substance, which is sufficiently flexible for purposes of being applied with the pad to curved body surfaces and yet which affords sufficient rigidity to stabilize the pad and prevent delamination, etc. (Col. 2, line 67 to Col. 3, line 2).

As explained above in connection with Mulhauser and discussed with the Examiner, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. As discussed above, a prosthetic material having a surface texture or porosity of approximately 10 μ m or more is not adhesion resistant, but rather is susceptible to adhesions with tissue or muscle.

As indicated above, claim 65 has been amended to further recite that both the barrier layer and the edge barrier have a surface texture and a porosity that are less than 10 μ m. Claim 53 has been amended in a similar manner.

As explained previously, Meier provides no teaching or suggestion as to any structural characteristics of the frame that would allow one of ordinary skill in the art to determine its adhesion resistant properties. Although Meier discloses that the frame may be formed from any

of various materials, Meier is silent as to the structural characteristics, such as surface texture and porosity, that affect its adhesion resistance, such that one of ordinary skill in the art would not consider the Meier frame as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. Additionally, Meier does not teach or suggest at least an edge barrier having a surface texture and a porosity that are less than 10 μ m as now positively recited in the claims. Thus, Meier does not disclose at least an edge barrier that inhibits the formation of adhesions with tissue and organs thereto.

In view of the foregoing, claims 53 and 65 patentably distinguish over Meier, such that the rejections under §102 should be withdrawn. Meier fails to at least disclose an adhesion resistant edge barrier as recited in each of the claims.

Claim 56 and claims 68-71 respectively depend from claims 53 and 65 and are patentable for at least the same reasons.

Rejections Under 35 U.S.C. § 103

Claims 48, 49, 51, 52, 57, 58, 63, 64, 69 and 70 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser '525 in view of Gianturco (US 5,258,000). Applicant respectfully traverse these rejections.

Without acceding to the propriety of the combination as suggested by the Examiner, claims 48, 49, 51 and 52 depend from claim 46 and are patentable for at least the same reasons set forth above. Similarly, claims 57 and 58 depend from claim 53 and are patentable for at least the same reasons set forth above; claims 63 and 64 depend from claim 59 and are patentable for at least the same reasons set forth above; and claims 69 and 70 depend from claim 65 and are patentable for at least the same reasons set forth above. Accordingly, withdrawal of these rejections is respectfully requested.

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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